

# - INSTRUCTIONS -

## Common Protocol Cover Form (section A) Completion Instructions

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**Note:** All the necessary forms for submission are located in the forms section of our website and should be downloaded each time you need one. This will ensure that the most recent version is submitted. Outdated versions will not be accepted.

The Common Protocol Cover Form is a combined submission form that is utilized by the Committees on Human Research, VCC and GCRC. This manual will only address the IRB submission portion (Section A). The data fields within the form automatically expand to allow additional text. Use the required fields for all comments –this may expand the form to additional pages which is acceptable.

### Section 1: Protocol/Project Title:

The title should reflect the title on the research protocol.

## Section 2: Investigator Information:

**1. Principal Investigator:** The name of the local principal investigator.

**2. Degree:** The degree of the principal investigator (i.e., MD, PhD etc.).

Enter the following contact information for the PI.

**Dept:**

**Phone:**

**E-mail:**

**Campus/Office Address:** Location where the Committee should send correspondence. This could be the PI or the designee for the study.

**Fax #**

**Department Chair** List the chair at time of submission.

**Is PI UVM Faculty?** If the PI is a UVM faculty member, please check "Yes". Many employees share appointments at both UVM and FAHC.

**Is PI FAHC Employee?** If the PI is a FAHC employee, please check "Yes". Many employees share appointments at both UVM and FAHC.

**Is PI UVM Employee only?** Check yes if applicable.

**Is PI UVM Fellow, Resident or Student?** Check "Yes" if applicable and complete section 15 once the rest of the form is complete. If the principal investigator is a student indicate whether Graduate or Undergraduate.

**\*NOTE:** Under normal circumstances only UVM or FAHC individuals can be PI. If you are not affiliated with either UVM nor FAHC, you must stop here and contact the RPO office for additional guidance.

**Do you want to appoint Primary Contact other than PI?**

Investigators wishing to appoint a contact for all IRB communications related to this protocol should check "Yes," and complete the contact information in the sections provided. Often times the **research coordinator** is the person who handles most of the administrative responsibilities of a study, acts as a liaison between the principal investigator, the sponsor, if applicable, and the IRB. These responsibilities can be assigned to someone on the study team, an administrator, or the principal investigator but is more often a data manager, clinical research associate, or research nurse. Regardless of the primary contact, the PI is still ultimately responsible for all aspects of the research and IRB submissions.

### Section 3: Brief Lay Language Summary:

Summarize the proposed research project. Use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) objectives or aims, and (2) a brief but specific description of the procedure(s) involving the human subjects. Do not exceed one single-spaced 8 ½ X 11" page.

**\*\*Example below\*\***

The primary objective of this study is to determine whether the efficacy of a 5 day course of high-dose oral methylprednisolone therapy will be equivalent to standard-of-care high-dose IV methylprednisolone for treatment of acute attacks (exacerbations) of MS. Subjects will be evaluated clinically to determine if they are having an exacerbation of their MS. Subjects will be randomized to blinded treatment with IV methylprednisolone plus oral placebo or oral methylprednisolone plus IV placebo for five days. Subjects will undergo physical exams, neurological exams, multiple sclerosis functional composite testing (25 ft walk, 9 hole peg-test and pasat-3 test) and laboratory testing (bloodwork and urine) at screening visit and periodically throughout the 1-year course of the study as outlined in the study protocol. Primary outcome measure is change in EDSS (disability) score from day 0 to day 28.

### Section 4: Type of Review:

**a. Indicate which type of review is requested.**

If **EXPEDITED** is checked: Research is expeditable if the research activities

(1) Present **no more than minimal risk** to human subjects

**AND**

(2) **Involve only procedures listed in one or more of the following categories:** (CHECK THE CATEGORY(IES) THAT APPLY.

**(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**

**a.** Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**(2) Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week: or

b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**(3) Prospective collection of biological specimens** for research purposes by noninvasive means.

**(4) Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

**(5) Research involving materials** (data, documents, records, or specimens) that have been collected, or will be **collected solely for nonresearch purposes** (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)

**(6) Collection of data from voice, video, digital, or image recordings** made for research purposes.

**(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3).

**b. Is this research developed and written by industry?**

(drug or device company - industry sponsored)

**Yes or No**

**c. Is this research developed and written by a UVM/FAHC researcher? Yes or No**

**b. Does the research involve the study of cancer or is it cancer-related?**

**Yes or No**

If **yes**, this research is also subject to a separate review by the Vermont Cancer Center. Click here, [Protocol Review Committee](#), for the requirements.

**e. Does the research involve the use of radioactive materials, radioisotopes, and/or radiation producing equipment?**

**Yes or No**

If **yes**, research is subject to a separate review by UVM's [Radiation Safety Committee](#). Or FAHC's Radiation Safety Committee.

**f. Does the research involve the use of any General Clinical Research Center (GCRC) facilities?**

**Yes or No**

If **yes**, research is subject to a separate review by the GCRC. Click here, [Scientific Advisory Committee](#), for the requirements.

**g. Does the research involve any work with biohazardous materials including but not limited to, infectious biological agents, toxins, pathogens, gene therapy or recombinant DNA?**

**Yes or No**

If **yes**, research is subject to a separate review by the Institutional Biosafety Committee. Click here, [Institutional Biosafety Committee](#), for the requirements.

## **Section 5: Other Key Personnel:**

Anyone who has contact with the subjects or their identifiable data.

**“Key Personnel” Must Include:**

PIs

Researchers in contact with subjects

Clinical research associates or coordinators (data managers and research nurses)

Anyone in contact with personally identifiable research information and

Anyone consenting subjects

**“Key Personnel” Might Include:**

Other clinicians in the clinic conducting the research or

Other laboratory staff in the lab conducting the research

**“Key Personnel” Never Includes:**

Cooperative group or sponsor staff (unless they are directly contacting our locally enrolled subjects).

**Note:** Please do not include people who are only expected to provide cross-coverage unless there is a very high likelihood that they will actually see or contribute to the research data of at least one subject. If you have any questions as to whether or not

someone should be listed as Key Personnel, please contact the IRB staff.

All Key Personnel must complete the UVM / FAHC Protections of Human Subjects in Research Tutorial before the protocol approval or re-approval will be released.

The names of all persons fitting the above descriptions should be listed in alphabetical order, by last name, if possible. Use an additional sheet if there are more than 12 key personnel.

**Faculty Sponsor** Fellows, residents, post-doctoral fellows, post-doctoral associates, post-doctoral trainees, and students (graduate or undergraduate) cannot conduct human subject research without having a faculty sponsor/instructor who is responsible for overseeing the research activities.

**Research Coordinator** Person who handles administrative responsibilities, and acts as a liaison between the PI, the sponsor and the IRB. Leave space blank if not applicable.

## Section 6: Source of Support:

Indicate all applicable sources of support by checking the appropriate box(es). If you have any questions about what source of support should be checked contact our office.

- a. **UVM/FAHC Department** – This category is internal funding provided by the PI's department. We see this type of support typically for investigator-initiated with no other support. This category is not subject to IRB fees.
- b. **UVM Grant or Contract processed by OSP Pre-Award Services (PAS)** – Non-Industry - These are usually federal or state funded. PAS assists the PI with the grant submission and the post-award management of those funds. It is important that you submit the corresponding grant proposal with the protocol submission as the IRB is required to review them for congruence. Institutional overhead is taken for this assistance and therefore this category is not subject to the IRB fees.
- c. **Industry-Funded Research processed through UVM OSP Pre-Award Services** – Typically all industry-sponsored contracts and negotiations are processed through the Office of Clinical Trials. However, in rare situations, industry sponsors and or PIs wish to have the funds processed through UVM's PAS. If your funds are processed through the PAS, be sure to complete section 9 of the form as your project may be subject to the IRB review fees.

- d. **Industry Sponsor is providing test-article or equipment (no funding)** – Sponsorship can take the form of materials not money. Here you would describe what is being provided. If there is no additional monetary support, this category is not subject to the IRB fees.
- e. **Industry-Funded Clinical Trial processed through FAHC OCTR** – All industry-funded protocols are to be processed through the Office of Clinical Trials as early in the process as possible. Contracts, billing plans, and budgets need to be developed and negotiated. This category is subject to the IRB fees.
- f. **Any Non-UVM and/or Non-FAHC Protocol (anytime we are acting as the IRB for an unaffiliated entity)** - On rare occasions the IRB is requested to act as an IRB of record for an unaffiliated entity. In those cases, the protocols are subject to the IRB fees regardless of the protocol's funding.
- g. **\*Provide the sponsor's billing information below. (not the local person)** – As mentioned above, based on protocol funding, some protocols are subject to the IRB fees. When they are subject, complete this section in full to allow us to create and forward the invoice to the sponsor.

## **Section 7: Subject Information:**

Recording an accurate list of the subject populations targeted for the research allows the Committees to ensure all applicable federal regulations are met. All of the following information should be provided in the protocol.

**a. Subject Information:** Enter the total number of subjects that are expected to enroll in the research study locally. This should be an estimate of the total accrual over the lifespan of the research. It should include an estimate that accounts for subjects who decline after consent or are screen failures as these subjects are considered “enrolled”. This information should be reflected somewhere in the protocol (usually the section for statistical analysis). Also this area should include the number of samples or medical records if data is being reviewed.

**The following elements should be included in the inclusion/exclusion section of the protocol.**

- **Male**
- **Female**
- **Students or Employees**
- **Normal Volunteers:** If the research expects to include subjects without a specific disease or condition, check this box. (Check this box for research that is only enrolling normal volunteers and

for research that will include normal volunteers in the control group.)

- **Other potentially vulnerable subjects:** Describe any other potentially vulnerable subjects not checked or listed above.
- **Persons with specific disorder:** In the protocol, if specific disorders are included in the eligibility section, please check this box and summarize the disease or condition. If there is a normal control group, check Normal Volunteers as well.
  
- **Adults:** Are 18 years old or older, specify ages
- **Minors (17 years or less):** Are 17 years old or younger, specify ages
- **Wards of the State**
- **Non-English Speaking**
- **Cognitively Impaired or Mentally Ill**
- **Pregnant Women**
- **Fetuses**
- **Prisoners**

- b. **Will Subjects be compensated?** If there is any compensation (compensation may be in the form of money or in other forms such as health care benefits, course points or course credit, travel expenses, bonuses, etc.) check “Yes”.

**If “Yes” Amount with disease/condition:** Enter the dollar amount given to subjects with the specific disease or condition, if any.

**If “Yes” Amount without disease/condition:** Enter the dollar amount given to subjects without a specific disease / condition or to normal volunteers, if any.

Other types of compensation: If there is any other compensation such as health care benefits, course points or course credit, travel expenses, bonuses, etc., please provide details in the box provided.

## **Section 8: Protected Health Information:**

The Committees on Human Research function as the IRB and the HIPAA Privacy Board for UVM and FAHC. One of the responsibilities of the Privacy Board is to review the use and disclosures of protected health information from a covered entity. Fletcher Allen Health Care is a covered entity. Protected Health Information (PHI) is any identifiable information (including demographic information), whether in oral, electronic or written form, related to a person's past, present or future physical or mental health

or condition; or past, present or future delivery of or payment for healthcare services. The HIPAA Privacy Rule allows for the creation, use and/or disclosure of PHI in the conduct of research with either (1) authorization of the individual or (2) waiver of the authorization as approved by a Privacy Board.

**8.a. Will this protocol access, use or disclose protected health information (PHI) from a covered entity?** For UVM and FAHC the covered entity is FAHC (and some UVM departments such as the Center for Health and Wellbeing, and the Luse Center for Communication). Check “Yes” or “No” as appropriate. Please note that PHI is only information from a covered entity, and not information that comes directly from the subject through interviews, surveys or questionnaires.

**If yes, complete the Authorization Cover Form, develop an Authorization for IRB review, or if you are requesting a waiver of consent, then you may apply for a waiver of authorization as well by completing the Request for Waiver of Consent / Authorization form Sections II and III.**

**If no, skip to #9.**

**8.b. Identifiers:** Includes any information in which the following 18 identifiers of the individual or of relatives, employers, or household members of the individual, are stated:

1. Names;
2. All geographic subdivisions smaller than a state;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical Record numbers;
9. Health Plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;

- 14. Web Universal Resource Locators;
- 15. Internet Protocol (IP) address numbers;
- 16. Biometric identifiers, including voice and finger prints;
- 17. Full face photographic images and any comparable images;
- 18. Any other unique identifying numbers, characteristics or codes.

If you are using or disclosing PHI, please indicate what level of PHI will be received or recorded, from one of the following options:

**With identifiers:** The research needs access to PHI from the covered entity.

**With limited identifiers:** The research is mostly anonymous and only records such PHI as ZIP codes, geocodes, and dates. This would be considered a Limited Data Set. Researchers who wish access to a Limited Data Set must contact FAHC to execute a Data Use Agreement (see forms page). FAHC will assist the researcher to identify a data custodian. The data custodian must be an agent of the covered entity (FAHC or other applicable covered entity) and independent of the research project. The data custodian creates the Limited Data Set prior to releasing to the researcher. The FAHC Privacy Officer should have a copy of the Data Use Agreement prior to release of the Limited Data Set to the researcher. Note: While the IRB needs to be aware of this information it does not assist in initiation of a limited data set nor execute the data use agreement. This occurs at the covered entity.

**NOTE:** If you check “with limited identifiers” you could have answered “No” to question 6.a, as no PHI is being used.

**Without any identifiers:** Researchers who wish access to de-identified PHI must contact the appropriate data custodian(s) (i.e., an individual who is an agent of FAHC and is independent of the research project) to de-identify the requested PHI. If there are no identifiers, as listed above in the dataset required for the research, then the research does not fall under the HIPAA regulations.

If you check “without any identifiers” you should have answered “no” in question 6.a.

## Section 9: Recruitment:

The recruitment methods and materials require review by the IRB. Any recruitment materials, advertisements, scripts, and posters need prior IRB review and approval.

**Good Practice:** If subjects or potential subjects see recruitment material, it usually requires pre- approval.

**a. How will subjects be recruited?** Subject recruitment has always been reviewed by the IRB. However, under the new HIPAA legislation, subject recruitment procedures need to be documented in greater detail as the Committee on Human Research functions as the IRB **and** the HIPAA Privacy Board.

**Check here if recruiting is not applicable to the research.** If your research does not involve recruitment (i.e., the research is using previously collected data, etc.) check this box.

**PI / Collaborators will recruit own patients** – Any FAHC Health Care Provider or his/her immediate practice group who has a direct treatment relationship with the patient and will recruit their own patients.

**PI will send an IRB approved letter to colleagues asking for referrals of potential subjects who are interested in the research study** – In this situation the investigator/study team cannot contact the interested subject directly since there is no treating relationship. The interested subject must contact the research team. This letter must have pre-approval by the IRB.

**PI will send an IRB approved letter to colleagues asking the physicians to send out IRB approved “Dear Patient” letter describing the research study.** The PI/ designee may draft a letter with the treating physician’s signature, but may not have access to the patient names or addresses for mailing purposes. The subjects must make first contact with the research staff if interested in the research study. The researchers cannot receive a list of subjects to contact or any names of subjects that were mailed the “Dear Patient” letter. This letter must have pre-approval by the IRB.

**Advertisements/media:** Research using any form of media to recruit subjects, including; newspapers, magazines, radio, or television, must be pre-approved by the IRB for its content. See Attachment B for guidance on development.

**PI is recruiting subjects for behavioral or non-clinical research.** Fill in as applicable.

**Other:** Describe any other recruitment methods.

**b. The PI Requests a Partial Waiver of Authorization for Recruitment Purposes:** If the investigator has no treatment relationship with the subject but needs access to protected health information for recruitment purposes, complete a Request for a Partial Waiver of Authorization for Recruitment Purposes form. See Section 8.B.7 for additional guidance.

## **Section 10: Consent Process:**

### **a. Type of Consent**

**i. Are you requesting a Waiver of Informed Consent?** If yes, complete a Request for a Waiver of Informed Consent/Documentation/Authorization form.

**ii. Are you requesting an Alteration of Informed Consent Procedures?** Deception is one example when consent would be altered. If yes, complete the Request for a Waiver of Informed Consent/Documentation/Authorization form Section I.

**iii. Are you requesting a Waiver of Documentation of Consent?** If yes, complete a Request for a Waiver of Informed Consent/Documentation/Authorization form.

**iv. Are you obtaining consent from a legally authorized representative?**

If yes, check the categories listed below. This information will help to clarify the consent process for those unable to consent for themselves.

### **b. Consent Process**

**i. Once a prospective subject is identified, who initiates the informed consent discussion and answers questions presented by the subject or the subject's family?** Either the PI or the PI's designee(s) need to be listed here. These persons should be listed as key personnel and complete the IRB Consent Module located on our website to better understand their role.

**ii. Where (in what setting) is the informed consent discussion begun? How much time is the subject given to decide?** Be specific about this question. Is the subject in a clinic, does the consentor speak with the subject on the phone? When does the subject get approached? For example in the case of a clinical trial are potential subjects approached right after diagnosis? Is the subject allowed time to think about participation?

**iii. Is the principal investigator present for the initial and subsequent informed consent discussions with the subject?**

**iv. What other method of documentation is used to record the informed consent process, in addition to the executed consent form?** There should be documentation that the initial and all subsequent consent discussions have been conducted. This could be in a dated note in the subject's research file or it could be part of a clinical note in their medical record. See an example of appropriate documentation of the informed consent process on our website. This was provided by Office of Clinical Trials Research.

## **Section 11: Protocol Information:**

The following information should be provided in the protocol.

**a. Study will begin:** Enter the proposed start date of the research locally.

**Study will end:** Enter the projected end date of the research.

**b. Is this a multi-institutional study?** Multi-Institutional refers to any institutions outside of the UVM/FAHC umbrella. Check "Yes" or "No" as applicable. Contact the IRB office to discuss ambiguous circumstances.

**If "Yes", list cooperating institutions here or in protocol.**  
List the cooperating institutions for multi-center trials initiated at UVM or FAHC.

**c. If this is a clinical trial, which phase of study is it?** Check the appropriate box.

### **d. Data Safety & Monitoring Plan**

Each research application, excluding "Exempt" research, must include a plan to assure the safety and welfare of research subjects, data integrity and confidentiality. The extent of monitoring research data will vary depending upon the risk/benefit ratio, sample size, and complexity of the research. The following section clarifies for the Committee what is in place for this purpose.

### **i. Recognizing and Responding to Risks**

Provide a description of how you will identify, evaluate and report safety information.

#### **1) Adverse Events**

- Adverse event data should be monitored to determine whether there is any change to the anticipated benefit-to-risk ratio of study participation and whether the study should continue as originally designed, should be changed, or should be

terminated. Consider the following when creating a plan to monitor adverse events.

- How will adverse events will be captured (i.e., subjects will be followed and asked about their change in health since their last study visit, subjects will be called after study visits, subjects will not be able to leave the clinic before certain safety measures are met, subject's medical records will be reviewed for events)?
- Who will monitor the research subjects? Specify staff and facilities which are available and adequate to handle adverse events.
- What will be the frequency of such a review process?
- What measures will be taken to ensure that the occurrence of illness or injury will be detected and treated?
- Describe procedures for communicating to the IRB, the study sponsor, and other appropriate entities the outcome of the reviews.

## 2) New Safety Information

- An assessment of external factors or relevant information (i.e., pertinent scientific literature reports or therapeutic developments, results of related studies) that may have an impact on the safety of study subjects or the ethics of the research study should be considered when creating a data and safety monitoring plan. Describe who will be responsible for collecting, analyzing and reporting external information. Include the frequency of such reviews (at a minimum at least annually) and specify sources or search engines that will be utilized. Describe procedures for communicating to the IRB, the study sponsor, and other appropriate entities the outcome of the reviews.

## 3) Unanticipated Problems to Subjects or Others

- It is the responsibility of the Principal Investigator to promptly report unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems) to the IRB. An unanticipated problem is an event or problem that is
  - 1) unexpected (*An event is unexpected if the information is **not included** in the current protocol, drug/device brochure or the informed consent.*)
  - 2) Possibly, probably, or definitely related to participating in research
  - 3) Poses a potential harm to **subjects or others.**

- Describe plans for assuring unanticipated problems are reported to the IRB. This would include identifying, evaluating and reporting (in addition to adverse events and new safety information which have been addressed separately in questions 1 and 2) any of the following: protocol deviations, complaint of a subject that indicates an unanticipated risk or which cannot be resolved by the research staff; any untoward event that affects the welfare or the privacy, confidentiality or other rights of research subjects, members of their family, or others; and any untoward event that presents a risk to investigators and research staff involved in the conduct of the research.

#### **4) Assuring Confidentiality**

- Describe how the confidentiality of subjects will be assured. Include a description of any issues specific to the study that might increase the risk of breach of confidentiality. For example, video/audiotapes, discovering information about the research subject that could be harmful if released such as mental illness, genetic information, sexual preference, drug abuse, etc.
- Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate.
- **Audio or Video Taping:** Describe how the audio/videotapes will be stored, how subjects' confidentiality will be maintained, and how the tapes will be disposed of when this research is complete. The use of audio or videotapes provides for a direct link to the subject. The IRB must clearly understand the need for the use of audio or videotapes, as well as the plans for storage and timeline/method for destruction of the tapes.

#### **a. Indicate how individual research subject data will be maintained?**

Research data, with or without PHI, should be kept secure. Record the ways in which the research data will be maintained and stored.

**For Hardcopy Data:** All paper and physically stored materials including research charts, films, x-rays, pictures, drug logs, computer disks and CDs, slides, and other specimens. List the security methods used for the research project's hardcopy data:

**Locked Suite:** The suite is generally inaccessible to the public and locked whenever the data is unattended.

**Locked Office:** The office is generally inaccessible to the public and locked whenever the data is unattended.

**Locked File Cabinet:** The cabinet is generally inaccessible to the public and locked whenever the data is unattended.

**Data Coded by PI or Research Team with a master list secured and kept separately:** For security issues, the hardcopy data is de-identified and requires a master list to identify the subjects. The master list is kept separately and accessible only to key personnel listed in section 3 of the Common Protocol Cover Form.

**Other:** Describe other security protections for hardcopy research data.

**For Electronic Data:** All electronically stored materials (especially databases). Note that computer disks and CDs containing research data are considered hardcopy data. List the electronic data security methods used for the research project's electronic data, if applicable:

**Secure Network:** The data is on a secured database that requires a user ID and password. Provide the network or server name where the data resides.

**Password Access:** The data is contained in a program or electronic folder that has password protection.

**Online data (i.e. forms, surveys):** Describe how research subjects' identity will be protected when utilizing the Internet to collect data.

**Other:** Describe other security protections for the electronic research data.

## ii. Identify who will be responsible for the data and safety monitoring?

- **Data Safety and Monitoring Board or Committee**

A **Data Safety and Monitoring Board (DSMB)** or **Data and Safety Monitoring Committee (DSMC)** is an external, independent committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a study to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another) that would warrant modification or termination of the study or notification to study subjects about new information that might affect their willingness to continue participation in the study. Typically, protocols that are industry-sponsored accrue subjects at

multiple sites and are required to have the appropriate resources to capture and report issues of safety.

**Note: DSMB/DSMC reports are required to be submitted to the IRB immediately upon receipt.**

- **Principal Investigator**
- **Other:** Provide detailed information if another individual (i.e. co-investigator) or entity (i.e. an informal committee or review process) will be responsible for data and safety monitoring.

**iii. What data or other information will be reviewed?**

Check those items that will be reviewed as a part of the data and safety monitoring plan. Include details regarding other data or information that will be reviewed that are not included on the list.

**iv. Are there criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study (i.e. “stopping rules)? If yes, please specify where in the protocol this information can be found. If the protocol does not include stopping rules please describe what criteria will be used for decision-making in order to minimize risks?**

Describe under what circumstances the PI and/or study sponsor will terminate the research study or the involvement of a given subjects in the research study. Address specific endpoint criteria (i.e., suicidal ideation for a depression study) that will result in patient removal from the study. Indicate what steps will be taken to ensure appropriate follow-up care of the subjects in the event an endpoint criteria is realized.

**v. What will be the frequency of the review?**

Indicate how often a review will be conducted. The frequency of reviews may not be stated in an industry-sponsored protocol please contact the sponsor for this information.

**vi. Will the sponsor be conducting data monitoring visits for this study?**

If there is a sponsor for the study (pharmaceutical company, cooperative group, etc.), will that sponsor perform site visits to UVM/FAHC to audit the research charts and local procedures?

**If “Yes”, how often?** The frequency of site visits is often not stated in the protocol and is specific to each sponsor. Please call the sponsor for this information.

## Section 12: Location of Research Activities:

Please check the following locations where research is expected to take place.

**FAHC / UHC Campus:** University Health Center, 1 South Prospect St.

**Gen. Clinical Research Center:** FAHC, MCHV Campus, Baird 7 Correctional Facility

**FAHC / MCHV Campus:** 111 Colchester Avenue. Specify department within FAHC.

**FAHC Outpatient Facilities:** Such as Timberlane, or Fanny Allen. Specify offsite location.

**UVM Campus:** University of Vermont, non-FAHC setting. Specify location.

**Schools/School Systems:** Provide names of individual schools or districts that have agreed to participation in the research.

**Other Locations:** All locations not captured above. Specify location.

## Section 13: Types of Procedures:

a. Please check all of the following procedures that will be performed in this protocol. Accurately checking these boxes is the best way to assist the Committees in performing prompt review of your research.

**1. Survey (mail, telephone, in-person):** Most human subject research has some form of survey. Surveys are typical to behavioral studies.

**2. Medical exams/medical histories**

**3. Deception \* see below** Check if there is any intentional deception. Deception typically involves withholding information from the potential subject and would require an alteration of the consent process. Section 10ii above refers to the completion of Request for a Waiver of Informed Consent/ Authorization/ Documentation Section I. Placebo use in research is not considered a deception as long as the subject is aware that there is a possibility of receiving a placebo and it is stated in the consent form.

**4. Observation:** Typically observation occurs in a portion of the research population, though it could potentially include the entire

subject group. Note: If videotaping is involved, videotaping should also be checked.

**5. Photographs**

**6. Audio Taping or videotaping:** If videotaping is required, observation should also be checked.

**7. Interviews**

**8. Focus Groups**

**9. Review of Records:** If it is likely that patients' past and current medical records will be reviewed, then check this box.

**10. Recording Identifiable Personal Data:** Indicate if there is any identifiable personal data. This data could come from either the covered entity (and therefore HIPAA is applicable) or directly from the subject.

**11. Electrocardiograms**

**12. Sensitive Data (criminal conduct, drug or alcohol conduct or use):** Please indicate if there is the possibility of uncovering sensitive data in the normal performance of this protocol. If there is the possibility of capturing child abuse, drug abuse, or criminal behavior please check here and specify.

**13. Blood:** Check this box if there will be any research-specific blood draws.

**a. Volume:** For the blood draws, please indicate the total volume that is expected to be drawn throughout the entire research timeframe.

**b. Over days, weeks?** Indicate the timeframe that encompasses the entire volume as stated above.

**14. Tissue or Blood (obtained solely for research):** If there is any tissue or blood obtained solely for research (i.e., not required for treatment on the study), check this box. Frequently these are extra procurements of tissue or blood and are not necessary for the subject's treatment but are typically used for future research.

Examples: Blood, tumor slides or blocks, fingernail clippings, etc.

**Type & Amount:** List the type of tissue (Blood, tumor slides or blocks, fingernail clippings, etc.) and the amount (i.e., 5ml, a 5 micron slice, the entire tissue sample) that is expected to be used for the research.

**15. Surgery:** Check here if the research involves any inpatient or outpatient surgery.

**16. Drug Administration:** Check here if there are any investigational or non-investigational drugs administered on this protocol. Also complete a list of the all the drugs in the table provided at the end of this section.

**17. Exercise:** Check here if there is any exercise required for the protocol.

**18. Diet:** Check here if there is any manipulation of the diet of the research subjects, whether restrictions or additions.

**19. Pathology Specimens:** If there are any pathology tests required by this protocol, such as blood tests, histopathological evaluations of tissues, necropsy evaluations, bacteriological or parasitological examinations, then check this box. The “Required Studies” section of the protocol should detail these requirements. Examples: drug level tests, hormone tests, standard blood chemistries, cancer evaluation (tissue or blood), evaluation of bone specimens.

**20. Cadavers / Autopsy Specimens:** If there is any involvement with cadavers or if the research requires additional autopsy procedures indicate as such here.

**21. Questionnaires:** Forms containing a set of related questions designed to gather data from a sample population.

**22. Pregnancy Tests:** If female subjects are required to undergo a pregnancy test prior to enrolling in the study (or at anytime throughout the protocol) check here.

**23. Collection of Urine and/or Feces**

**24. HIV Testing:** If subjects must receive an HIV test prior to enrolling in the study (or anytime while on the protocol), check here. Note: The FAHC policy on HIV testing should be referenced in your protocol.

**25. Ultrasound or Laser:** Any use of ultrasound or laser should be indicated by checking this box.

**26. X-Rays**

**27. Use of Radiation:** Any use of radiation or radiation therapy, should be indicated by checking this box.

**28. Use of Radioactive Substances:** Check this box if the research uses of any radioactive substances such as radioactive seeds, radioactive tracers or radioactive implants.

**29. MRI (for treatment studies):** Any use of MRI for treatment purposes should be indicated here.

**30. Functional MRI or MRI (not for treatment studies):** Any use of MRI for purely research purposes should be indicated here.

**31. Other:** Check here for any other types of procedures that apply, and specify the procedures in the box.

**b. COMPLETE THIS SECTION ONLY if blood is being drawn outside of a clinical area in coordination of other study procedures. If not applicable skip to Section 14. If the only procedure is blood drawing outside of clinical areas, STOP and complete the “Blood Drawing for Non-Clinical Laboratory Research” instead of this form.**

*The IRB has developed guidance [“Blood Draws in Non-Clinical Settings”](#) for researchers who are collecting blood outside of the clinical area.*

**Why is blood being collected from subjects in a non-clinical setting?**

**b.1. Name of person(s) collecting the blood.**

- b.2. Explain experience/training of the collector.**  
**b.3. Where will the collection take place?** List all potential sites.  
**b.4. Confirm by checking below that you will follow the “Approved Standard Practices for Obtaining Blood” which is located within the guidance noted above.**  
**b.5. Will the samples be linked with identifiers or codes?**  
If yes, explain why identification is necessary and how the data will be protected.  
**b.6. How, where and for how long will the samples be maintained? (will samples be secure?)**

## **Section 14: FDA Regulated Items:**

- a. Does this investigation use an Investigational New Drug (IND)?**  
See IND section 12.A of the research manual.

If “Yes” complete the following information.

**Name of Drug:**

**Drug Company (Sponsor):**

**FDA IND Number:** This number would typically be located within the protocol or the Investigational Drug Brochure, otherwise contact the sponsor for this information and provide written documentation.

**Investigator Holding IND:** Typically this is from the sponsoring company.

If “No”, proceed to 14.b.

**Check “NA”** if the research does not use any drugs, and proceed to Section 12.b.

- b. Does this investigation use an FDA-approved drug in an investigational manner? (i.e., different indication)**

This is more often the case in investigator initiated studies.

If “Yes” complete the following information

**Name of Drug:**

**Drug Company:**

**If “Yes”, does its use meet all of the following conditions below for exemption?**

1. It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

2. it is not intended to support a significant change in the advertising of the product;
3. it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreased the acceptability of the risks) associated with the use of the drug product;
4. it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];
5. it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and
6. it does not intend to invoke 21 CFR 50.24.

If **“Yes”** it is exempt from filing an IND.

If **“No”** it requires an exemption submission to the FDA. If it has been previously filed, complete the following:

**FDA IND Number:** Contact the FDA for this information.

**Investigator Holding IND:** Typically this is from the drug company or the PI of the research study.

**c. Will an Investigational Device be Used?** See IND section 12.B of the research manual.

If **“Yes”** complete the following information.

**Name of Device:**

**Manufacturer (Sponsor):**

**FDA IDE Number:** This number would typically be located within the protocol or the Investigational Device Brochure, otherwise contact the sponsor for this information and provide written documentation.

**Investigator Holding IND:** Typically this is from the sponsoring company.

If **“No”**, please verify that you can answer **“Yes”** to the question **“Exempt from IDE?”**.

**Check “NA”** if the research does not use any devices, and proceed to Section 13.

**Exempt from IDE?** To be exempt from an IDE the investigation must meet **one** of the following seven conditions.

1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or

investigated in accordance with the indications in labeling in effect at that time.

2. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

3. A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing:

(i) is noninvasive;

(ii) does not require an invasive sampling procedure that presents significant risk;

(iii) does not by design or intention introduce energy into a subject, and

(iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

4. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

5. A device intended solely for veterinary use.

6. A device shipped solely for research on or with laboratory animals and labeled in accordance with Sec. 812.5 (c).

7. A custom device as defined in Sec. 812.3 (b), unless the device is being used to determine safety or effectiveness for commercial distribution.

**If “Yes”, which exemption # from below.** If the research is exempt from requiring an IDE, provide the category which pertains to the use of the device.

**d. Is Device Significant Risk?**

See the research manual for a discussion of [Significant Risk Devices](#).

**Is Device Non-Significant Risk?**

See the research manual for a discussion of [Non-Significant Risk Devices](#).

**e. Is this a Humanitarian Use Device (HUD)?**

See the research manual for discussion of [HUDs](#).

**f. List all (investigational and non-investigational) drugs and devices here.**

## **Section 15: Disclosure of Financial Interest:**

If the results of the study provide any financial gain or there is a financial interest for the PI or for key personnel, you must document that conflict here and in the consent form.

- a. Do any members of the investigative team or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed \$5,000 in any twelve month period? Select “Yes” or “No” as applicable.**  
If yes, disclosure in the consent form is required. Policy has suggested language.
- b. Do any members of the investigative team or members of their immediate families have an equity interest that exceeds \$5,000 in value or represents more than 2% ownership interest in the sponsoring entity?**  
If yes, disclosure in the consent form is required. Policy has suggested language.
- c. Do any members of the investigative team or members of their immediate families have any intellectual property rights (inventorship, patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s), or other material(s) that will be involved in this research?**  
If yes, describe in the box provided.
- d. Has the principal investigator or key personnel completed an FDA Financial Disclosure Form?** If yes, attach a copy. If no, proceed to next section.

## **Section 16: Faculty Sponsor:**

If this is a student's, resident's or fellow's research project, the project must have a Faculty Sponsor. The Faculty Sponsor must review the proposal, sign off on the form, and understand that they are responsible for the overall conduct of the research project. Please list the name, phone number, address, and email of the Faculty Sponsor. The faculty sponsor must sign and date this form in the lines provided.

**Thesis or Dissertation Committee:** All research requiring a Thesis or Dissertation Committee review must be reviewed and approved by that committee **before** it may be sent to the IRB for review and approval. If applicable, list the date of the Committee's review here.

## **Section 17: Investigator's Agreement:**

By signing this agreement, the PI is agreeing to a list of PI Responsibilities that reflect the Common Rule regulations.

## **Section 18: Attachments to this Common Protocol Cover Form**

This checklist area **is optional** to document the various attachments that are being submitted. In some instances, study sponsors require such documentation.